510(k) Summary for
Dimension Vista® C1IN Flex® reagent cartridge
Dimension Vista® C1IN CAL
Dimension Vista® C1IN CON

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K072965

DEC 2 1 2007

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer:
Dade Behring Marburg GmbH
Emil-von-Behring Str. 76
35041 Marburg, Germany

Contact Information:
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714-6101
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: October 19, 2007

2. Device Name: Dimension Vista® C1IN Flex® reagent cartridge
Dimension Vista® C1IN CAL
Dimension Vista® C1IN CON

Classification: Class II; Class II; Class I
Product Code: DBA; JIS; JJX
Panel: Immunology (82) and Clinical Chemistry (75)

3. Identification of the Legally Marketed Devices:

Dade Behring N Antisera to Human C1 Inhibitor– K960257
Dade Behring N Protein Standard PY – K962410
Dade Behring N/T Protein Control PY – K962407

4. Device Descriptions:

Dimension Vista® C1IN Flex® reagent cartridge
Proteins contained in human body fluids form immune complexes in an immunochemical reaction with specific antibodies. These complexes scatter a beam of light passed through the sample. The intensity of the scattered light is proportional to the concentration of the respective protein in the sample. The result is evaluated by comparison with a standard of known concentration.

Dimension Vista® C1IN CAL
C1 Calibrator is a lyophilized, human plasma based product containing C1 Inhibitor (C1IN).

Dimension Vista® C1IN CON
C1 Control is a lyophilized, mid-level, human plasma based products containing C1 Inhibitor (C1IN).

5. Device Intended Uses:

Dimension Vista® C1IN Flex® reagent cartridge:
The C1IN method is an *in vitro* diagnostic test for the quantitative measurement of C1 inhibitor in human serum and plasma on the Dimension Vista® System. Measurements of C1 Inhibitor aid in the diagnosis of hereditary angioneurotic edema (increase blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

Dimension Vista® C1IN CAL:
The C1IN CAL is an *in vitro* diagnostic product for the calibration of the C1 Inhibitor (C1IN) method on the Dimension Vista® System.

Dimension Vista® C1IN CON:
C1 Inhibitor Control is an assayed, mid level, intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of C1 Inhibitor (C1IN).

6. Medical device to which equivalence is claimed and comparison information:

The Dimension Vista® C1IN Flex® reagent cartridge, Dimension Vista® C1IN CAL and Dimension Vista® C1 CON are substantially equivalent to the Dade Behring N Antisera to Human C1 Inhibitor assay (K960257), N Protein Standard PY (K962410), and N/T Protein Control PY (K962407), respectively. The Dimension Vista® C1IN assay, like Dade Behring N Antisera to Human C1 Inhibitor is an *in vitro* diagnostic test for the quantitative measurement of C1 Inhibitor in human serum and plasma.

7. Device Performance Characteristics:

The Dimension Vista® C1IN assay was compared to the Dade Behring N Antisera to Human C1 Inhibitor assay on the BN ProSpec® System by evaluating serum and plasma samples with concentrations ranging from 0.03 to 0.39 g/L. Regression analysis of these results yielded the following equation.

Method Comparison Study

Comparative Method	n	Slope	Intercept g/L	Correlation Coefficient
N Antisera to C1Inhibitor on the BN ProSpec® System	196	0.915	0.006	0.993

8. Conclusion:

These studies demonstrate correlation and equivalent performance between the Dade Behring N Antisera to Human C1 Inhibitor assay and the Dimension Vista® C1IN assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 1 2007

Dade Behring, Inc.
c/o Ms. Kathleen Dray-Lyons
Manager, Regulatory Affairs and Compliance
Glasgow Site
P.O. Box 6101
Newark, DE 19714-6101

Re: k072965
Trade/Device Name: Dimension Vista C1IN Flex reagent cartridge
Dimension Vista C1IN CAL
Dimension Vista C1IN CON
Regulation Number: 21 CFR 866.5250
Regulation Name: Complement C1 inhibitor (inactivator) immunological test system
Regulatory Class: Class II
Product Code: DBA, JIT, JJX
Dated: October 19, 2007
Received: October 29, 2007

Dear Ms. Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072965

Device Name: **Dimension Vista® C1IN Flex® reagent cartridge**
Dimension Vista® C1IN CAL
Dimension Vista® C1IN CON

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Prescription Use __X__ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K072965